

**ClinicalTrials.gov Title Page**

**Document:** Informed Consent Form

**Official Study Title:** The Effect of Supplemental Nutrition Assistance Program-Education on the Dietary Intake of Low-income Indiana Participants

**NCT #:** NCT03436784

**Document Date:** September 28, 2015

RESEARCH PARTICIPANT CONSENT FORM  
The NEP Long-Term Study Sequel  
Dr. Heather Eicher-Miller  
Department of Nutrition Science  
Purdue University



**What is the purpose of this study?**

You are invited to be in a research study of the Indiana Nutrition Education Program (NEP). You were selected as a possible participant because you are eligible for the Supplemental Nutrition Assistance Program (SNAP), also known as food stamps, and are interested in attending NEP lessons. The purpose of this study is to learn more about the impact of NEP lessons. This study is funded by the AgSEED grant from Purdue University. We ask that you read this form and ask any questions you may have before agreeing to be in the study. The study is being conducted by Dr. Heather Eicher-Miller and Rebecca Rivera from the Nutrition Science Department of Purdue University. We expect to enroll up to 800 participants in this study.

**What will I do if I choose to be in this study?**

If you agree to be in this study, you may be asked to wait 13-14 months before receiving NEP lessons. We would ask you to do the following things:

- Complete an initial survey, a second survey in 4-10 weeks, and a third survey in 13-14 months
- Complete a dietary assessment including 2 dietary recalls on foods you ate in the past 24 hours on 2 different days and 1 diet questionnaire on foods you typically ate in the past 1 year or past 30 days during the week of the initial survey, during the week of the second survey, and during the week of the third survey
- Allow us to measure your height and weight at all three survey time points
- Provide contact information (phone number, email address and/or mailing address) to NEP Assistants for the purpose of keeping in contact throughout the study period

**How long will I be in the study?**

The length of participation in the study is 13-14 months. At each of the three assessment time points, the survey including height and weight measurements will take about 30 minutes to complete; each dietary recalls will take about 15-30 minutes to complete; and the diet questionnaire will take about 60 minutes to complete.

**What are the possible risks or discomforts?**

The risks of participating in this study are minimal and not any more than are encountered in everyday life. Although there may be potential risk of breach of confidentiality, safeguards will be in place to reduce this risk and are described below.

**Are there any potential benefits?**

There are no direct benefits to participating in this study; however, your participation may provide general knowledge about the impact of NEP lessons.

**Will I receive payment or other incentive?**

You will receive payment for participating in this study: \$5.00 gift certificate after taking the first survey in person and \$10 gift certificate after each of the second and third in person surveys. You will also receive a \$15.00 gift certificate for completing the first diet recall and diet questionnaire and \$10 for completing the second diet recall for up to a total value of \$30 at for the first assessment time point and up to \$35 for each of the second and third assessment time point. Participants may receive up to a total value of \$100 for completing the in person survey and online dietary assessment during the week of all three survey time points.

Participants who complete the final survey before January 1<sup>st</sup>, 2017 will be entered into a \$500 raffle. The odds of winning are approximately 1 in 480 and one \$500 check will be awarded. The winner will be randomly chosen by April 1<sup>st</sup>, 2017. If researchers are unable to contact the winning participant through their NEP Assistant after 3 attempts within one week (phone call, mailing, email), another participant will be randomly chosen. You may decline the \$500 if you are chosen. Your name, address, and social security number or taxpayer identification number will need to be shared with Purdue University Department of Nutrition Science business office only if you win and accept the \$500 and only for dispersing the \$500 check. If you win and accept the \$500, you must complete the Institutional Review Board Human Subject Receipt Log, which will be provided by researchers. Non-resident alien recipients will have to complete information within the Glacier Tax Compliance software system ([www.online-tax.net](http://www.online-tax.net)) to assess tax reporting and withholding requirements. Other than previously stated, no payment or additional action is required to enter the raffle. Participation in additional research or other consideration is not necessary. Void where prohibited or restricted by law. Subject to all federal, state, and local laws.

**Will information about me and my participation be kept confidential?**

The project's research records may be reviewed by departments at Purdue University responsible for regulatory and research oversight. The records of this study, including this consent form and the paper copies of the surveys, will be kept private and locked in filing cabinets in a locked office on the Purdue University campus for three years after the conclusion of the study. Consent forms will be kept separately from any paper surveys or other documents. The information provided on the participant forms will be entered into a study database and stored in a secure server space at Purdue University. The primary and co-investigators will not have access to information that would make it possible for them to identify you or to link your name with data you provide. Only an identification number will link together the three surveys for data analysis. Only your NEP Assistant will have a record connecting your name and participant ID number, which will be securely locked in the county Extension Office and destroyed upon the completion of the study. Reports containing information from this study will not include any information that would make it possible to identify you. Compensation for participation in the study will require your name and signature on a payment log. This log will be kept confidential and only the Purdue University Department of Nutrition Science business office will receive it. Your name will not be connected to any of your responses collected from surveys.

**What are my rights if I take part in this study?**

Your participation in this study is voluntary. You may choose not to participate or, if you agree to participate, you can withdraw your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your

current or future relations with the Indiana NEP, NEP educator, Extension, with any other federal or state program, or with Purdue University. If you decide to participate, you can choose not to answer any question or choose to withdraw from the study at any time without affecting those relationships. If you withdraw from the study you may continue taking the NEP lessons.

**Who can I contact if I have questions about the study?**

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact:

Dr. Heather A. Eicher-Miller, PhD  
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If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email ([irb@purdue.edu](mailto:irb@purdue.edu)) or write to:

Human Research Protection Program - Purdue University  
Ernest C. Young Hall, Room 1032  
155 S. Grant St.,  
West Lafayette, IN 47907-2114

**Documentation of Informed Consent**

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research project and my questions have been answered. I am prepared to participate in the research project described above. I will receive a copy of this consent form.